

DRUG POLICY

Cobenfy® (xanomeline/trospium)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Cobenfy is a muscarinic agonist indicated for the treatment of schizophrenia in adults.

POLICY

Criteria for Initial Approval

Schizophrenia

Authorization of 12 months may be granted for the treatment of schizophrenia when all of the following criteria are met:

1. Patient must be 18 years of age or older
2. Diagnosis of schizophrenia

OR

1. Continuation of coverage if medication was initiated in the inpatient setting

Continuation of Therapy

Schizophrenia

Authorization of 12 months may be granted for treatment in adult patients requesting authorization for treatment of schizophrenia who achieve or maintain a positive clinical response.

Other

Cobenfy (xanomeline/trospium) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Cobenfy (xanomeline/trospium) 50/20 mg capsule	60 capsules per 30 days	Starting dose of 50/20 mg orally twice daily $\geq$ 2 days, then increase to 100mg/20 mg orally twice daily $\geq$ 5 days. May be increased based on response and tolerability to a maximum dose of 125/30 mg orally twice daily.
Cobenfy (xanomeline/trospium) 100/20 mg capsule	60 capsules per 30 days	
Cobenfy (xanomeline/trospium) 125/30 mg capsule	60 capsules per 30 days	
Cobenfy (xanomeline/trospium) 50/20 mg & 100/20 mg starter pack	1 pack (56 capsules) per 28 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Cobenfy. Prescribing information. Bristol-Myers Squibb Company; September 2024. Accessed October 17, 2024.
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- Jauhar S, Johnstone M, McKenna PJ. Schizophrenia. *Lancet*. 2022;399(10323):473-486. doi: 10.1016/S0140-6736(21)01730-X
- Kaul I, Cohen EA, Miller AC, et al. Maintenance of efficacy of KarXT (xanomeline and trospium) in schizophrenia. Abstract presented at: 2024 Annual Congress of the Schizophrenia International Research Society; April 3-7, 2024c; Florence, Italy. Abstract F264.
- Kaul I, Sawchak S, Correll CU, et al. Efficacy and safety of the muscarinic receptor agonist KarXT (xanomeline-trospium) in schizophrenia (EMERGENT-2) in the USA: results from a randomised,

double-blind, placebo-controlled, flexible-dose phase 3 trial. *Lancet*. 2024a;403(10422):160-170. doi: 10.1016/S0140-6736(23)02190-6

- Kaul I, Sawchak S, Walling DP, et al. Efficacy and safety of xanomeline-trospium chloride in schizophrenia: a randomized clinical trial. *JAMA Psychiatry*. 2024b:e240785. doi: 10.1001/jamapsychiatry.2024.0785

POLICY HISTORY

Policy #: 05.05.70

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Reviewed: June 2026

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Current Effective Date: June 27, 2025